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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/782,594

02/12/2001

John R. Bianchi

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04/04/2008

REGENERATION TECHNOLOGIES, INC.

c/o MCANDREWS, HELD & MALLOY

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CHICAGO, IL 60661

EXAMINER

PREBILIC, PAUL B

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

04/04/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/782,594	BIANCHI ET AL	
	Examiner	Art Unit	
	Paul B. Prebilic	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Double Patenting

Upon review of copending application 09/941,154, it was noted that claim 79 was cancelled in the most recent amendment dated November 19, 2007. For this reason, the double patenting rejection was withdrawn. However, a review of related applications to the present application reveals that applications 09/905,683, 10/387,322, and 09/941,154 present potential double patenting issues in that the claimed subject matter therein is quite similar to the presently claimed subject matter. The Applicant is respectfully requested to apprise the Examiner of any double patenting conflicts among this application, the applications mentioned *supra*, and any other applications or patents that they are aware.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siebels et al (EP 0517030) in view of Coates et al (US 5,989,289). Siebels discloses an assembled bone implant made by assembling separate bone implant pieces together to form an implant by aligning bores of adjacent pieces. Next, Siebels introduces pins into the aligned bones to hold the implant pieces together; see Figures 1 and 2 and page 8 of the translation, first full paragraph and page 9 of the translation. Siebels also

discloses that “the hollow space is filled with bone material or bone cement for the purpose of a radial anchoring of the ring”; see page 5 of the translation. Also, on page 11 of the translation, Siebels discloses that “extraneous bone material, or the patient’s own bone material” can be used to fill the cavity. However, Siebels fails to disclose making the implant pieces of cortical bone and mentions a preference for fiber-reinforced plastic (see page 3, last 4 lines of the translation) or carbon-fiber reinforced plastic (see the second full paragraph on page 6).

Coates, however, teaches that is was known to make similar spinal implants out of allograft or autograft cortical bone because of its superior properties in vivo; see the abstract, column 2, line 33 to column 3, line 45, column 7, lines 18-43, and column 11, lines 42-61. Therefore, it is the Examiner’s position that it would have been obvious to make the disks and pins of the Siebels implant out of cortical bone for the same reasons the Coates teaches doing the same.

Regarding claims 28-30, the spacers of Coates can have osteogenic material of demineralized bone and/or allograft bone applied to them such that the pin(s) of Siebels, which would be made into bone because of the teachings of Coates, would also have these materials applied to them. Any segment thereof could be said to be made of cortical bone. “Allograft” is a homograft (i.e. from the same species) that is allogenic (i.e. genetically distinct) to the recipient; see Merriam-Webster OnLine at www.m-w.com/cgi-bin/dictionary?book+=Dictionary&va=allograft. Since the bone of Coates is capable of being used as a bone graft unit upon the death of the individual, it is considered an allograft bone portion with respect to another human being to the

extent that this language can be given patentable weight. The site or source of the material is relative to how it can be used and is not indicative of the material itself because the bone implants of Coates are allogenic with respect to another human being. For these reasons, the separated bone pieces are grafts and allografts when these terms are given their broadest reasonable interpretation. The claim language requiring "machined" bone portions is not structurally distinguishing from that disclosed by Coates because it does require any particular structure in the device; see MPEP 2113 that is incorporated herein by reference.

Response to Arguments

The Applicant's arguments filed November 5, 2007 have been fully considered but they are not persuasive in all cases.

The Applicant argues that Siebels only means making implants out of plastic even when it states "solid disks can be manufactured of any biologically compatible material." This argument is not considered persuasive because the plain language of Siebels does not suggest such a limited understanding and because the use of plastics is considered to be mere exemplification or preference for making the device. Moreover, Coates provides the motivation to make the implant pieces of Siebels out of bone.

Next, the Applicant argues that the prior art references teach away from the combination suggested by the Examiner because Siebels requires an "extraordinarily easy" way of making the implants thereof. However, the Examiner asserts that Siebels is referring more to the assembly and sizing of the device just prior to surgery rather

than the overall process of making. Furthermore, if the prior art had difficulty in making bone grafts from the perspective of Coates, than Coates at least implicitly can be said to overcome such difficulties. For this reason, there would be nothing stopping an ordinary artisan from applying the teaching of Coates to that of Siebels to arrive at the claimed invention. Moreover, a preference for a certain material, as in Siebels, is not a teaching away from other materials; see MPEP 2123 (II) that is incorporated herein by reference thereto.

Moreover, the Examiner asserts that Siebels desires easily assembleable disks that enable the surgeon to quickly assemble pre-manufactured disks into an appropriately sized implant. Coates, on the other hand, states that implants made with bone have had problems due primarily to their shapes and cancellous bone make-up. Coates discloses one example of a bone dowel that was not stable due to shape and cancellous bone make-up see the discussion of Cloward on column 3. Assembly of the implant pieces was not an issue. Coates solved the problems of the prior art by making the implant primarily of cortical bone and making the implant into a rectangular shape with vertebra engaging teeth and ridges to prevent migration. Consequently, the Examiner asserts that Coates is discussing an entirely different issue than that of Siebels. For these reasons, the Applicant's line of reasoning is not considered persuasive.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Paul Prebilic/
Paul Prebilic
Primary Examiner
Art Unit 3774